REMARKS/ARGUMENTS

Claims 8 and 9 appear in this application. Subsequent to this amendment, claims 8 and 9 are pending.

Favorable reconsideration is respectfully requested in view of the following remarks.

Rejection of Claim 9 under 35 U.S.C. 102(b) as being anticipated by WO 96/14058 to Oshlack et al. (Page 2 of the Office Action)

This rejection is respectfully traversed.

Concerning the rejection under 35 U.S.C. 102 of claim 9, Examiner stated that "the features upon which the Applicants rely (i.e., extrusion step which takes place outside the machine...) are not recited in the rejected claim(s)." Applicants respectfully disagree and draw Examiner's attention to the language of Applicants' claim 9. That a heating step for maturing a mixture is carried out outside the extruding machine is implicit in the language of claim 9. Step c) notes that the matured mixture is introduced into the kneading area of an extruding machine. Thus thereby indicating that the step for maturing the mixture takes place outside an extruding machine and is different from heating the mixture for extrusion.

In contrast, the cited art does not disclose a heating step outside the extruding machine. Applicants respectfully draw Examiner's attention to page 27, line 23, page 44, line 1, and Figure 9 of the cited art. As shown in Figure 9 of the cited art the heating step takes place inside the extruding machine. Additionally, in Pellet Manufacture on page 27 and Granulation Manufacture

on page 44 of the cited art, it is shown that extruder heating zones are used for the heating step. This heating step is for the purpose of rendering extrusion easier, not for maturing the mixture.

Additionally, Examiner stated that he is still not persuaded by the results of Table I, and that "absent the necessary statistical analysis of the data, it is impossible to determine the numbers presented in Table I." Applicants respectfully disagree. Examination of results collected in Table I shows a significant pattern that the active substance releases slower when increasing the conditions of the maturing step, i.e. duration and temperature. And that enables the increase of the quantity of active substance for a given release curve without increasing the volume of the tablet.

For at least the reasons set forth above, Applicants respectfully disagree that the cited art's disclosure reads on the method of making particles as claimed by Applicants.

Rejection of Claims 8 and 9 under 35 U.S.C. 103(a) as being unpatentable over WO 96/14058 to Oshlack et al. (Page 4 of the Office Action)

This rejection is respectfully traversed.

Concerning the rejection under 35 U.S.C. 103 of claim 9, Examiner stated that "there is no evidence to prove that [the heating step discussed in the cited art] takes place inside the extrusion machine". Applicants respectfully disagree and draw Examiner's attention to page 27, line 23, page 44, line 1, and Figure 9 of the cited art. As shown in Figure 9 of the cited art the heating step does take place inside the extruding machine. Additionally, in Pellet Manufacture on page 27 and Granulation Manufacture on page 44 of the cited art, it is shown that extruder heating zones are used

for the heating step. This heating step is for the purpose of rendering extrusion easier, not for maturing the mixture.

In contrast, in Applicants' claim 9 a heating step for maturing the mixture is carried out outside the extruding machine and is different from heating the mixture for extrusion. Applicants draw Examiner's attention to the language of Applicants' claim 9. That a heating step is carried out outside an extruding machine is implicit in the language of claim 9. Step c) notes that the matured mixture is introduced into the kneading area of an extruding machine. Thus thereby indicating that the step for maturing the mixture takes place outside an extruding machine and is different from heating the mixture for extrusion.

Concerning the rejection under 35 U.S.C. 103 of claim 8, Examiner stated that the "cited art teaches that their process eliminates the spheronization step (p 5, l 25)." Applicants respectfully draw Examiner's attention to page 5, lines 24-26, page 17, lines 23-30, page 18, lines 1-14 and claim 18 of the cited art. The cited art actually proposes to teach the elimination of "the need of a spheronization step." (*See* p 18, l 14 and p 5, l 25). As shown in claim 18 of the cited art, sustained-release melt extruded multi-particulates can be non-spheroidal, and therefore do not need to be spheroidal in shape.

In contrast, Applicants' claim 8 is for an apparatus for obtaining spheroidal particles without any additional spheroidal shaping step.

Additionally, Examiner stated that the cutting tool claimed by Applicants are the equivalent to a typical cutting blade at the exit of the extrusion machine. The Examiner supported her statement

by noting that the cited art states that the multiparticulate system can be in the form of granules, spheroids or pellets depending on the extruder exit orifice (p 17, l 28-30), and therefore, although it is not specified, it must be an equivalent blade setup.

Again, Applicants respectfully draw Examiner's attention to the fact that the cited art nowhere suggests a tool for chopping which comprises cutters as defined in claim 8 to obtain spheroidal particles without the need for any additional spheroidal shaping step. The cited art simply states that "exiting strands can be reduced into particles using a hot wire cutter, guillotine, etc. (p 17, l 25-26)." In contrast, Applicants' claim 8 requires, a tool "equipped with cutters in the form of blades having a first and second face parallel with one another, the first of which is inclined towards the second, thus forming a cutting edge, the second face being recessed so as to leave a strip of a width of less than 1 mm which comprises the cutting edge whereby the shape of the particles obtained by chopping the extruded filaments is directly spheroidal without any additional shaping step." Nowhere in the cited art is such a tool suggested.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.